

### REMARKS

This is a Supplemental Response to the final Office Action mailed September 8, 2004. Claims 1 to 51 are pending. Claims 1 to 3, 5, 7, 13 to 47, 50 and 51 have been cancelled herein without prejudice. Applicants maintain the right to prosecute any of the cancelled claims in any related application claiming the benefit of priority of the subject application. New claim 52, which depends from claim 10, has been added. Thus, upon entry of the Supplemental Response, claims 4, 6, 8 to 12, 48, 49 and 52 are under consideration.

A certified copy of European Application No. EP 98 101203.2, filed January 23, 1998, was submitted with Applicants previous Response. Applicants respectfully request that the certified copy be entered into the record.

Applicants thank the Examiner for the Interview and subsequent discussions. The amendments and new claim conform the claims with the subject matter indicated to be allowable by the Examiner in the Interview, in the final Office Action mailed September 8, 2004, and in subsequent discussions with the examiner. Applicants respectfully request entry of this Supplemental Response because the amendments and new claim place the case in better condition for allowance or for consideration on appeal.

#### Regarding the Amendments

The amendment to the specification was made in order to delete reference to an "egg cell." The amendment, which deletes a particular term from the specification, therefore does not add new matter. Furthermore, as the amendment places the claims in better condition for allowance or for consideration on appeal, entry thereof is respectfully requested.

The claim amendments were made to address various informalities or are supported throughout the specification. In particular, the amendment to claims 4 and 6 to recite "[a]n isolated nucleic acid molecule encoding a human Rhesus D antigen contributing to or indicative of the weak D phenotype, said nucleic acid molecule carrying at least one missense mutation, as compared to wild type Rhesus D antigen set forth as SEQ ID NO:41," was made in view of the cancellation of claim 1. The amendment to claims 4, 6, 8 and 49 to recite either "of the amino acid sequence encoded by SEQ ID NO:41 (Figure 2)" or "with reference to SEQ ID NO:41" was made in order to more clearly indicate the sequence to which the recited positions refer. The amendment to claim 4 to recite "or a combination of said substitutions" was made in order to

provide adequate antecedent basis for this language in claim 49. The amendment to claim 6 to recite "or a combination of said missense mutations" is supported, for example, by claim 3, as originally filed. The amendment to claim 8 to recite "667" instead of "677" was made to correct a typographical error. The amendment to claim 11 is supported, for example, at page 11, second and third paragraphs, which discloses bacterial, yeast cells, fungal cells and insect cells. The remaining amendments to claims 8 to 11, 48 and 49 provide correct claim dependencies, antecedent basis or greater clarity and, therefore, were made to address informalities. Thus, as the amendments were made to address various informalities or are supported by the specification, no new matter has been added. Furthermore, as the amendments place the claims in better condition for allowance or for consideration on appeal, entry thereof is respectfully requested.

Regarding the New Claim

Support for new claim 52 can be found, for example, at page 18, second paragraph, which discloses that a particular use of the nucleic acid, vector or Rhesus D antigen of the invention, is assessment of the affinity, avidity and/or reactivity of monoclonal anti-D antibodies, or of polyclonal anti-D antisera, or of anti-globulin or of anti-human-globulin antisera. Support for claim 52 can also be found, for example, at page 19, second paragraph, which discloses a method for characterizing monoclonal antibodies or polyclonal antisera employing the nucleic acid; and at page 19, fourth paragraph, which discloses that the characterization can comprise the determination of reactivity, sensitivity, avidity, affinity, specificity and/or other characteristics of antibodies and antisera. Thus, new claim 52 does not add new matter. Furthermore, as new claim 52 places the claims in better condition for allowance or for consideration on appeal, entry thereof is respectfully requested.

European Priority Application, EP 98 101203.2

A certified copy of European Application No. EP 98 101203.2, filed January 23, 1998, was submitted with Applicants previous response. Applicants respectfully request that the certified copy be entered into the record, and that in view of the perfection of the priority claim to the January 23, 1998, filing date of European Application No. EP 98 101203.2, that the

priority claim be acknowledged as requested in the Petition for Corrected Filing Receipt, filed October 13, 2004.

**I REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

The rejection of claims 1 to 5, 7, 9 to 12, 14, 48, 50 and 51 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed. The Examiner maintains that the specification allegedly does not enable the full scope of the claims.

The specification adequately enables the claims for the reasons of record. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 1 to 3, 5, 7, 13 to 47, 50 and 51 have been cancelled, and claims 4, 6, 8 to 10, 48 and 49 have been amended as set forth above.

In view of the amendments to claims 4, 6, 8 to 10, 48 and 49, that the Examiner has indicated in the record that claims 6, 8 and 49 would be allowable if rewritten to be independent, and that the Examiner further indicated in the Interview that the claims, if amended as set forth above would be allowable, the grounds for rejection are moot. Consequently, claims 4, 6, 8 to 10, 48 and 49 are adequately enabled and the rejection under 35 U.S.C. §112, first paragraph, is requested to be withdrawn.

The rejection of claims 1 to 5, 7, 9 to 12, 14, 48, 50 and 51 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description, is respectfully traversed. The Examiner maintains the rejection for the reasons of record.

Claims 1 to 5, 7, 9 to 12, 14, 48, 50 and 51 are adequately described for the reasons of record. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 1 to 3, 5, 7, 13 to 47, 50 and 51 have been cancelled and claims 4, 6, 8 to 10, 48 and 49 have been amended as set forth above.

In view of the amendments to claims 4, 6, 8 to 10, 48 and 49, that the Examiner has indicated in the record that claims 6, 8 and 49 would be allowable if rewritten to be independent, and that the Examiner further indicated in the Interview that the claims, if amended as set forth above would be allowable, the grounds for rejection are moot. Consequently, an adequate written description of claims 4, 6, 8 to 10, 48 and 49 is provided and the rejection under 35 U.S.C. §112, first paragraph, is requested to be withdrawn.

## II. REJECTIONS UNDER 35 U.S.C. §102 and 103(a)

The rejection of claims 1, 3 to 5, 9, 12, 50 and 51 under 35 U.S.C. §102(a) as allegedly anticipated by Legler *et al.* (Transfusion 38:434 (1998)) is respectfully traversed. The Examiner indicates that Legler *et al.* allegedly describe "a polynucleotide that encodes a human Rhesus D antigen contributing to or indicative of the weak D phenotype....," and that allegedly "the priority date of instant application is December 18, 1998." [see Office Action, page 15]

The cited Legler *et al.* reference was published in May 1998. The subject application has a priority date of January 23, 1998, for the claimed subject matter, for the reasons set forth in the Petition for Corrected Filing Receipt, filed October 13, 2004. As evidence that Applicants are entitled to the benefit of January 23, 1998, priority date, submitted herewith is a certified copy of European Application No. EP 98 101203.2, filed January 23, 1998, which discloses the claimed subject matter.

In view of the fact that the claimed subject matter is disclosed in European Application No. EP 98 101203.2, and that the cited Legler *et al.* reference was published after the filing of European Application No. EP 98 101203.2, Legler *et al.* (Transfusion 38:434 (1998)) is not available as prior art against any claims of the subject application. Accordingly, as Legler *et al.* is not available as prior art against any claims of the subject application, the rejection under 35 U.S.C. §102(a) over Legler *et al.* (Transfusion 38:434 (1998)) is improper and must be withdrawn.

The rejection of claims 1, 2 and 10 to 12 under 35 U.S.C. §103(a) as allegedly unpatentable over Legler *et al.* in view of Sambrook *et al.* (Molecular Cloning, 1989, Cold Spring Harbor Laboratory, CSH, NY, Ch. 17) is respectfully traversed. The Examiner indicates that the secondary reference (Sambrook *et al.*) adds the limitations missing from Legler *et al.*, thereby allegedly rendering these claims obvious.

As set forth above, Legler *et al.* (Transfusion 38:434 (1998)) was published in May 1998. The subject application has a priority date of January 23, 1998, for the claimed subject matter, as evidenced by the certified copy of European Application No. EP 98 101203.2. In view of the fact that Legler *et al.* (Transfusion 38:434 (1998)) was published after the January 23, 1998, filing of European Application No. EP 98 101203.2, Legler *et al.* is not available as prior art

against any claims of the subject application. Accordingly, as Legler *et al.* is not available as prior art against any claims of the subject application, Legler *et al.* (Transfusion 38:434 (1998)) can not be cited under 35 U.S.C. §103.

The claims would not have been obvious in view of Sambrook *et al.* alone. Here, Sambrook *et al.*, *inter alia*, fail to teach or suggest a nucleic acid molecule encoding a human Rhesus D antigen, nor a nucleic acid molecule encoding a human RHD antigen having a missense mutation. Thus, Sambrook *et al.* fail to teach or suggest the claimed nucleic acid molecules, vectors or methods. Absent the requisite teaching or suggestion, the claims would not have been obvious in view of Sambrook *et al.* at the time of the invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

**CONCLUSION**

In summary, for the reasons set forth herein, Applicants maintain that claims 4, 6, 8 to 12, 48, 49 and 52 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

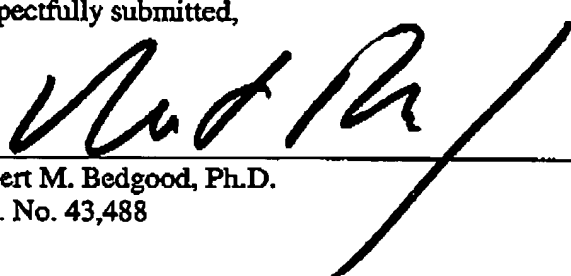
If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any additional fees, or make any credits, to Deposit Account No. 50-2212.

Respectfully submitted,

Date:

4-7-05

  
Robert M. Bedgood, Ph.D.  
Reg. No. 43,488

PILLSBURY WINTHROP SHAW PITTMAN LLP  
11682 El Camino Real  
Suite 200  
San Diego, CA 92130  
Telephone: (858) 509-4065  
Facsimile: (858) 509-4010